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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/539,092

Filing Date: June 15, 2005

Appellant(s): PETERMANN ET AL.

Robert M. Barrett
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 15, 2009, appealing from the Office action mailed April 2, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,475,539	DeWille et al.	11-2002
4,212,893	Takahata	7-1980

PURAC. 2001.

<http://web.archive.org/web/20010411064329/www.purac.com/products/index.html>

Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives.
“Lactic acid and its ammonium, calcium, potassium, and sodium salts.” World Health Organization Technical Report Series, 1974, No. 539

Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag

Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932

(9) Grounds of Rejection

Clarification Note: The examiner notes that there is a typographical error in claims 7 and 9. The lactic acid is written as L-(+) lactic acid. It is understood that all claims are to the L(+) form of lactic acid, regardless of how written.

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 5-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWille et al. (6,475,539) in view of PURAC (PURAC. 2001).

<http://web.archive.org/web/20010411064329/www.purac.com/products/index.html>

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DeWille et al. teach a nutritional formula that comprises a protein source, a carbohydrate source, a lipid source, and lactic acid. The formula in its liquid state has a pH of 3.0-4.6 (col. 6 lines 13-47). The solution may be directly acidified. That is, the pH of the solution may be adjusted by the addition of the acid, not fermentation (col. 15 lines 9-34). The nutritional formula may be provided as a ready-to-feed form, concentrate, or powder (col. 10 lines 26-30). Protein sources taught for use in the invention include whey protein and casein. The whey protein is used as a concentrate or isolate, which, as an essentially undenatured protein, is considered to be intact (col. 11 lines 36-50).

Regarding claims 7-9, DeWille et al. teach that the formula is prepared by first forming a protein/carbohydrate/oil mixture that is then acidified with an edible acid (col. 20 lines 1-9).

Regarding claims 10 and 11, the statements of intended use for the methods are not considered to patentably distinguish over the prior art. DeWille et al. teach preparing acidified nutritional formula by directly adding lactic acid to the nutritional formula (col. 15 lines 9-34). Further, low pH in foodstuffs is known to inhibit microbial growth (col. 6 lines 8-10).

Regarding claim 13, the amount of acid in the invention encompasses the range of percentages as claimed by applicants when calculated on a dry weight basis using claims 1 and 7 of DeWille et al. As DeWille et al. teach lactic acid for use in their invention, and their formula has a pH in the range overlapping the range claimed by Applicant's, it would have been expected that the amount of lactic acid needed to

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provide a pH as claimed by DeWille et al. would fall within the range claimed by Applicants.

DeWille et al. are silent as to their invention comprising L(+) lactic acid and to the formula being an infant formula.

Purac teaches the availability of edible L(+) lactic acid solution. The FCC products are indicated to be foodsafe.

One of ordinary skill in the art at the time the invention was made, desiring to acidify the invention of DeWille et al. with lactic acid, would have found it obvious to use L(+) lactic acid to provide the acidification. L(+) lactic acid was known in the art for addition to foodstuffs, and lactic acid is specifically taught as an acidulent in the nutritional formula of DeWille et al. Applicant is doing no more than using a known compound for its intended use in order to provide the predictable result of acidifying a foodstuff. Therefore, the combination of DeWille et al. the PURAC products FCC 50, 80 or 88 would have been obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the invention of DeWille et al. being an infant formula, one of ordinary skill in the art at the time the invention was made, wishing to provide a complete nutritional product for infants rather than children 13 months and older as taught by DeWille et al. (col. 10 lines 55-59) would have been able to modify the nutritional profile of DeWille et al. in order to provide a nutritional formula that met the nutritional needs of infants. One of ordinary skill, working from the teachings of DeWille et al., would have found it obvious to provide a shelf stable product that met the nutritional needs of

infants. These modifications would not have required undue experimentation, and would have been expected to result in an appropriately acidified infant nutritional formula.

Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) – lactic acid as taught by the WHO in order to result in an infant formula with higher acidity for improved digestion.

Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. “The Use of Lactic Acid Milk in Infant Feeding.” The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of PURAC (PURAC. 2001.

<http://web.archive.org/web/20010411064329/www.purac.com/products/index.html>
with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

Purac teaches edible L(+) lactic acid that is in compliance with all major food codices.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) lactic acid as taught by Purac to result in an infant formula with higher acidity for improved digestion. Applicant is utilizing a known compound, L(+) lactic acid, for its intended use as a food acidulant in order to provide the obvious combination of an acidified infant nutritional formula. This combination is further considered to obvious as there would be no undue experimentation required to utilize the L(+) lactic acid where the addition of lactic acid is specifically taught by Schwartz.

Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the

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pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahata (4,212,893) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. **Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).**

Takahata teaches an acidified whole milk beverage comprising whole milk and an organic acid (Abstract). Organic acids taught include lactic acid (col. 2 lines 32-36). The final pH of the beverage taught is within the range of 2.5 to 4.5 (col. 2 lines 25-27).

Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

Takahata is silent as to the enantiomeric ratio of lactic acid present in his composition.

The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized L (+) – lactic acid in the beverage taught by

Takahata in order to result in a beverage that may be marketed to the widest possible audience, including infants.

(10) Response to Argument

Claims 1, 2, 5-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWille et al. (6,475,539) in view of PURAC (PURAC. 2001. <http://web.archive.org/web/20010411064329/www.purac.com/products/index.html>).

Appellant argues that DeWille fails to disclose or suggest a nutritional infant formula directly acidified by the addition of L(+)-lactic acid.

Regarding the direct acidification, DeWille teaches that an embodiment of their invention comprises an acid system, the acid system further comprising lactic acid (col. 6 lines 37-42). At col. 15 lines 9-34, DeWille speak to the addition of the food acids to their nutritional formula. The formula may be acidified by any known acidification agent, including food grade acids. Food grade acids listed include lactic acid. One of ordinary skill would have recognized that the teaching of the addition of food grade acid to a foodstuff is “direct acidification” of the foodstuff. That is, the foodstuff is acidified directly by the addition of an acid, in this case lactic acid.

Regarding the invention of DeWille et al. being an infant formula, one of ordinary skill in the art at the time the invention was made, wishing to provide a complete nutritional product for infants rather than children 13 months and older as taught by DeWille et al. (col. 10 lines 55-59) would have been able to modify the nutritional profile

of DeWille et al. in order to provide a nutritional formula that met the nutritional needs of infants. One of ordinary skill, working from the teachings of DeWille et al., would have found it obvious to provide a shelf stable product that met the nutritional needs of infants. These modifications would not have required undue experimentation, and would have been expected to result in an appropriately acidified infant nutritional formula.

Appellant further argues that DeWille does not teach the addition of L(+)-lactic acid as claimed. In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The selection of L(+) lactic acid for addition to foodstuffs where lactic acid is specifically taught as an acidulant in the nutritional formula of DeWille et al. would have been obvious to one of ordinary skill in the art at the time the invention was made. Applicant is doing no more than using a known compound for its intended use in order to provide the predictable result of acidifying a foodstuff. Therefore, the combination of DeWille et al. and the PURAC products FCC 50, 80 or 88 would have been obvious to one of ordinary skill in the art at the time the invention was made.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The availability of L(+)-lactic acid for addition to foodstuffs was known in the art at the time Appellant's invention was made. The selection of a commercially available food-grade lactic acid for addition to a foodstuff where the addition of lactic acid is known is considered an obvious matter of choice.

Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

Schwartz teaches the addition of lactic acid to milk to be fed to infants. Schwartz was published in 1926, and the enantiomeric makeup of the USP lactic utilized at that time is unclear. The WHO document teaches that the amount of lactic acid for use in foodstuffs to be consumed by humans is not limited. There are 3 forms of lactic acid, D(-)-lactic acid, L(+)-lactic acid, and DL-lactic acid. The WHO specifically teaches that

D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants. Therefore, the only remaining choice for lactic acid that one would administer to infants would be L(+)-lactic acid. There is no other form of lactic acid available.

Appellants argue that the WHO teaches away from DL-lactic acid being administered to infants, and that no part of the WHO document teaches that infants can utilize L(+)-lactic acid, therefore, one would not include any lactic acid in foods to be administered to infants.

Again, as Schwartz clearly teaches the addition of lactic acids to foodstuffs to be administered to infants, and the WHO specifically teaches that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants, one of ordinary skill would have recognized that only L(+)-lactic acid was suitable for addition to infant foodstuffs. Simply stated, there is no other form of lactic acid that is suitable for use in infant foodstuffs, rendering the choice of L(+)-lactic acid an obvious one to one of ordinary skill.

There is no hindsight reconstruction required, as all of the elements of Appellant's invention were known in the art at the time the invention was made to have been used for the same purpose which appellant is claiming.

Wong is used in the rejection to provide evidence that milk contains whey proteins and casein. Wong is not used as prior art for the rejection, and therefore should not be regarded as deficient.

Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of PURAC (PURAC. 2001.

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Schwartz teaches the addition of lactic acid to milk to be fed to infants. Schwartz was published in 1926, and the enantiomeric makeup of the USP lactic utilized at that time is unclear.

PURAC teaches a foodgrade L(+)lactic acid. One of ordinary skill in the art at the time the invention was made wishing to provide lactic acid for use in infant foodstuffs would have found it obvious to utilize a food grade lactic acid as taught by PURAC to do so. Applicant is utilizing a known compound, L(+)lactic acid, for its intended use as a food acidulant in order to provide the obvious combination of an acidified infant nutritional formula.

The combination of prior art references does not need to disclose the advantages or benefits of the combination, as Appellant alleges. The combination of the prior art needs to provide for all of the limitations of Appellants claims, which it does.

In response to appellant's argument that the examiner's conclusion of

obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The availability of L(+)-lactic acid for addition to foodstuffs was known in the art at the time Appellant's invention was made. The selection of a commercially available food-grade lactic acid for addition to a foodstuff where the addition of lactic acid is known is considered an obvious matter of choice.

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The WHO document teaches that the amount of lactic acid for use in foodstuffs to be consumed by humans is not limited. There are 3 forms of lactic acid, D(-)-lactic acid, L(+)-lactic acid, and DL-lactic acid. The WHO specifically teaches that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants. Therefore, the only remaining choice for lactic acid that one would administer to infants would be L(+)-lactic acid. There is no other form of lactic acid available.

Appellants argue that the WHO teaches away from DL-lactic acid being administered to infants, and that no part of the WHO document teaches that infants can utilize L(+)-lactic acid, therefore, one would not include any lactic acid in foods to be administered to infants.

Again, as Takahata clearly teaches the addition of lactic acids to foodstuffs, and the WHO specifically teaches that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants, one of ordinary skill would have recognized that only L(+)-lactic acid was suitable for addition to infant foodstuffs. Simply stated, there is no other form of lactic acid, other than the L(+), that is suitable for use in infant foodstuffs, rendering the choice of L(+)-lactic acid an obvious one to one of ordinary skill.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nikki H. Dees/

Examiner, Art Unit 1794

Conferees:

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794

/Benjamin L. Utech/
Primary Examiner